

JUN 25 2007

Appln. No. 10/796,215

Attorney Docket No. 10000-353
Client Reference No. PA-5377-RFB**II. Remarks**

Claims 1-35 of the present application are pending and rejected. With the remarks provided herewith, Applicants respectfully request reconsideration and withdrawal of all rejections to the claims.

The Applicants thank the Examiner for the case interview on June 25, 2007 via phone. As mentioned during the interview, the claimed invention provides reduced kinking of a stent introducer system during deployment of a stent. The specification of the present application is provided in pertinent part, describing an aspect distinguishable from any of the cited references, as follows:

In this embodiment, the first tubular portion 13 comprises a non-rigid polymer tube made of a material with superior column strength. Possible materials include, but are not limited to, PEEK, polyvinyl chloride (PVC), polyimide, and polyurethane. The outside diameter (O.D.) of the first tubular portion 13 is approximately .07" (1.78 mm) in this example, and is configured to take up most of the inside diameter (I.D.) of the passageway 27 of the introducer catheter 11 so as to provide support thereto and reduce the likelihood and severity of kinking in the introducer catheter 11. Maximizing the pusher catheter O.D. also adds rigidity and column strength for pushing the stent from the catheter.

Specification paragraph [0022] of the present application, ll. 9-17 (emphasis added).

Responsive to the rejections of claims 1-35 under 35 U.S.C. § 103 based on the combination of U.S. Patent No. 6,425,898 to Wilson et al. ("*Wilson*"), and U.S. Patent No. 5,702,418 to Ravenscroft ("*Ravenscroft*"), the combination does not teach all of the elements of the claimed invention, and such combination and rejections are improper.

The combination of *Wilson* and *Ravenscroft* does not teach all of the elements of the claimed invention. For example, each of independent claims 1, 11, 23, 29, 30, and 35 recites a first tubular portion being a "non-rigid" polymer tube. Neither *Wilson* nor *Ravenscroft*, alone or in combination, teaches a first tubular portion being a "non-rigid" polymer tube. *Wilson* teaches that a proximal portion/end (16) is made of stainless steel to give the shaft the "necessary" rigidity or stiffness it "needs" to effectively push out the stent. See *Wilson* col. 5, ll. 40-44 (emphasis

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added). Moreover, *Ravenscroft* teaches a "stiff portion 15" that the Examiner has combined with the teachings in *Wilson* for the obviousness rejection. In fact, *Ravenscroft* describes that the stiff portion 15 has "limited flexibility so the catheter 11 can readily be pushed from the handle 12 through the patient's vessel with little risk of kinking." *Ravenscroft*, Col 5, ll. 23-30. Absent the teachings in *Wilson* and *Ravenscroft*, the first tubular portion may be a non-rigid polymer tube because its outside diameter (O.D.) is configured to take up most of the inside diameter of the introducer catheter 11 so as to provide support thereto and reduce the likelihood and severity of kinking in the introducer catheter 11. *Specification paragraph [0022] of the present application*, ll. 9-17. Maximizing the O.D. also adds rigidity and column strength for pushing the stent from the catheter. *Id.* Thus, *Wilson* and *Ravenscroft*, alone or in combination, do not teach each of the elements as recited in the claimed invention.

The combination of *Wilson* and *Ravenscroft* is improper because the references teach away from each other. The prior art must be considered in its entirety, including disclosures that teach away from the claims (M.P.E.P. § 2143.02) and the proposed modification cannot render the prior art unsatisfactory for its intended purpose or change the principle of operation of a reference (M.P.E.P. § 2143.01). *Wilson* teaches that a proximal portion/end (16) is made of stainless steel to give the shaft the necessary rigidity or stiffness it needs to effectively push out the stent. See *Wilson*, col. 5, ll. 40-44 (emphasis added). It is clear that the proximal end 16 requires rigidity to effectively push out the stent. Moreover, page 4 of the Detailed Action refers to PEBAX™ of the stiff portion 15 in *Ravenscroft* as the material to be combined with *Wilson* to satisfy the obviousness rejection.

However, combining the material of the stiff portion 15 of *Ravenscroft* with *Wilson* is improper. *Wilson* clearly requires rigidity to effectively push out the stent. See *Wilson*, col. 5, ll. 40-44. Simply combining *Wilson* with a material that is non-rigid or that may have aspects of non-rigidity (e.g., the Examiner suggested PEBAX™) is contrary to the teachings in *Wilson* and thus improper. Based on the teachings in *Wilson*, a proximal end 16 comprised of a non-rigid material would not effectively push out the stent and would negate the functional purpose of the distal portion 18, providing flexibility. Additionally, the resulting stent delivery apparatus of

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the combination having a proximal end 16 of non-rigid material would more than likely result in an inoperable device due to the non-rigidity of proximal end 16. See Figure 5 of *Wilson*.

The obviousness rejection is improper because the teachings in *Wilson* are contrary to the claimed invention even though the kinking problems may be similar. Each of the independent claims of the present application recites a first tubular portion being a "non-rigid" polymer tube. As mentioned above, *Wilson* clearly requires rigidity to effectively push out the stent. See *Wilson*, col. 5, ll. 40-44. As mentioned in the present application, the first tubular portion may be a non-rigid polymer tube because its outside diameter (O.D.) is configured to take up most of the inside diameter of the introducer catheter 11 so as to provide support thereto and reduce the likelihood and severity of kinking in the introducer catheter 11. *Specification paragraph [0022] of the present application, ll. 9-17*. This maximizes the O.D. as it adds rigidity and column strength for pushing the stent from the catheter. *Id.* Hence, rigidity is not required in the first tubular portion as the O.D. is maximized to take up most of the inside diameter of the introducer catheter. As the present application and *Wilson* have opposing approaches to similar problems, the rejection is improper.

Claims 2-3, 5-10, 24-28, and 31-34 depend generally from claims 1, 23, or 30. Thus, claims 2-3, 5-10, 24-28, and 31-34 are allowable for the reasons provided above.

Therefore, claims 1-35 are in a condition for allowance and such action is earnestly solicited.

June 25, 2007

Date

Respectfully submitted,

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